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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,417	03/04/2002	Bernd Riedl	BAYER 16 P4	3172
23599	7590	11/03/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,417

Applicant(s)

RIEDL ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 39-53 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,6,12 and 39-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/30/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

The following is responsive to Applicant's amendment received August 4, 2004.

Claims 13-38 are cancelled. No new claims are added. Claims 1-12, 39-53 are currently pending.

Claims 2, 5, 6, 12, 39-53 are withdrawn from consideration.

The previous claim objection set forth in paragraph 1 of the office action mailed Feb. 10, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, first paragraph, set forth in paragraph 2 of the office action mailed Feb. 10, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth in paragraph 6 of the office action mailed Feb. 10, 2004 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Feb. 10, 2004 with the following additional comment:

It is Applicant's position that the prior art fails to disclose or fairly suggest the claimed invention. Specifically, Applicant argues the broad disclosure of Salituro provides no direction to incorporate a substitute on a remote cyclic ring that conforms to L1 of urea. The broad disclosure at col. 2, lines 15-40 indicates substituents can appear on R3; however R3 can be many things other than a cyclic structure and the compounds of formula I of Salituro et al, encompass

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many compounds other than ureas. In that there is no direction from the broad or specific teachings of Salituro et al. to substitute the remote cyclic ring of a urea compound, there is clearly no direction to select any of the required substituents (-SO₂R_x, -C(O)R_x and -C(NR_y)R_z) that appear on the ureas employed in the present invention and therefore, the compounds and the methods claimed herein are unobvious.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully submits that despite the broad disclosure, Salituro et al., disclose and fairly suggest the claimed method. Salituro et al. teach a method of treating rheumatoid arthritis by administering a compound represented by formula (1), wherein Salituro et al. disclose preferred p38 inhibitors to be administered, with compound 20 being one of those preferred inhibitors (please note the compound 20 is embraced by the claims). Please see the abstract, col. 2, lines 1-45; col. 8, compound 20; col. 40, lines 36-38. Salituro et al. do not specifically disclose that the phenyl groups of compound 20 are substituted as required by the claims; however, the Examiner refers to col. 2, lines 1-40, where Salituro et al. teach and thus suggest that the aromatic rings may be optionally substituted with substituents such as CON(R₃)₂; COR₃ or SO₂NR₃. The Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the phenyl groups of preferred compound 20 not only because Salituro et al. directs one of skill in the art to make such a substitution but also because one of ordinary skill in the art would reasonably expect the substitutions to not alter the

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compound's p38 inhibitory activity, thereby treating patients suffering from rheumatoid arthritis.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Claims 1, 3, 4, 7-11 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Nov. 1, 2004

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Robert H. Fog